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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/981,998	05/11/98	PULST S	232.00010120

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EXAMINER	
GOLDBERG, J	
ART UNIT	**PAPER NUMBER**
1655	27

DATE MAILED: 04/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	08/981,998	PULST, STEFAN M.	
	Examiner	Art Unit	
	Jeanine A Enewold Goldberg	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-7 and 62-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *59* is/are allowed.

6)☒ Claim(s) *1-3,5-7 and 62-64* is/are rejected.

7)☒ Claim(s) *61* is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

1. This action is in response to the papers filed February 20, 2001.

2. Currently, claims 1-3, 5-7, 59, 61-64 are pending. All arguments have been thoroughly reviewed but are deemed non-persuasive for the reasons which follow.

3. Any objections and rejections not reiterated below are hereby withdrawn.

4. This action contains new grounds of rejection.

Priority

5. As the claims currently stand, it is the examiner's position that Claims 1-3, 5-7, 59, 61-63 are afforded the priority of May 1997. Whereas Claim 64 is afforded the priority of October 1996.

6. The examiner notes that the response asserts that certain parts of certain sequences are deemed earlier priority dates.

For the purpose of clarity, the sequences which are found in the pending claims are provided the following priority dates.

SEQ ID NO: 1 nucleotides 1-516	October 8, 1996
SEQ ID NO: 2 nucleotides 163-4098 (coding portion)	October 8, 1996
SEQ ID NO: 4 nucleotides 50-3454 (coding portion)	May 8, 1997
SEQ ID NO: 4	May 8, 1997
SEQ ID NO: 5	May 8, 1997

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-3, 5 and newly added 62-63 are rejected under 35 U.S.C. 102(b) as being anticipated by Imbert et al. (Nature Genetics, November 1996).

Imbert et al. (herein referred to as Imbert) teaches a polypeptide of 90 amino acids which is encoded by the nucleic acid of SEQ ID NO: 5. The nucleic acids from between 921-1190 of the instant application are 100% identical to the amino acids from 207-296. Imbert teaches a nucleic acid sequences which is 99.8% identical to SEQ ID NO: 1 nucleotides 1-499 and thus would hybridize under high stringency conditions (limitations of Claim 5). Imbert teaches a nucleic acid sequence which is 88.1% identical (ie., substantially the same nucleotide sequence) to the nucleic acid sequence of SEQ ID NO: 2 with a best local similarity of 98.5%.

Response to Arguments

The response traverses the rejection. The response asserts that Imbert is not prior art to the portion of the present application which was disclosed in 08/737,084. This argument has been reviewed but is not convincing because as stated in the MPEP 706.02 "If the application is a continuation-in-part of an earlier U.S. application, any claims in the new application not supported by the specification and claims of the parent

application have an effective filing date equal to the filing date of the new application. Any claims which are fully supported under 35 U.S.C. 112 by the earlier parent application have the effective filing date of that earlier parent application". In essence, one claim is entitled to one priority date. As outlined above, the instant claims are directed to embodiments which are entitled to different dates. Thus, the claim has not been fully supported by the earliest date, therefore the later date is the effective filing date.

Specifically Imbert teaches a nucleic acid sequences which is 99.8% identical to SEQ ID NO: 1 nucleotides 1-499 and thus would hybridize under high stringency conditions (limitations of Claim 5). While SEQ ID NO: 1 positions 1-516 have priority to October 1996, the entire claim is provided the date of May 1997.

Thus for the reasons above and those already of record, the rejection is maintained.

8. Claims 1-3, 5-6 and newly added 62, 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Pulst et al. (Nature Genetics, November 1996).

Pulst et al. (herein referred to as Pulst) teaches a nucleic acid which is 99.8% identical to the nucleic acid sequence of SEQ ID NO: 1 nucleotides 1-499 and thus would hybridized under high stringency conditions (limitations of Claim 5). Pulst also teaches a mouse sequence which is 100% identical to the nucleic acid sequence of SEQ ID NO: 4 nucleotides 50-3454 and thus would hybridize under high stringency conditions (limitations of Claim 5). Pulst also teaches a nucleic acid sequence which is 100% identical to the nucleic acid sequence of SEQ ID NO: 2 (limitations of Claim 6).

Pulst also teaches a nucleic acid sequence which is 77.9% identical to the sequence of SEQ ID NO: 4 (limitations of Claim 6). Oligonucleotides were end-labelled, FISH was performed and cDNA clones were isolated with P-labelled probes (pg. 275, col. 1)(limitations of Claim 11). Pulst teaches several different methods for identifying nucleic acids encoding SCA2 protein including FISH, and hybridization of (CAG)10 oligonucleotides followed by cloning and sequencing (pg. 275). Pulst also teaches primers which were derived from SEQ ID NO: 2 and SEQ ID NO: 4 (pg. 275, para. 6).

Response to Arguments

The response traverses the rejection. The response asserts that Pulst is not prior art to the portion of the present application which was disclosed in 08/737,084. This argument has been reviewed but is not convincing because as stated in the MPEP 706.02 "If the application is a continuation-in-part of an earlier U.S. application, any claims in the new application not supported by the specification and claims of the parent application have an effective filing date equal to the filing date of the new application. Any claims which are fully supported under 35 U.S.C. 112 by the earlier parent application have the effective filing date of that earlier parent application". In essence, one claim is entitled to one priority date. As outlined above, the instant claims are directed to embodiments which are entitled to different dates. Thus, the claim has not been fully supported by the earliest date, therefore the later date is the effective filing date.

Specifically, Pulst et al. (herein referred to as Pulst) teaches a nucleic acid which is 99.8% identical to the nucleic acid sequence of SEQ ID NO: 1 nucleotides 1-499 and

thus would hybridized under high stringency conditions (limitations of Claim 5). Pulst also teaches a mouse sequence which is 100% identical to the nucleic acid sequence of SEQ ID NO: 4 nucleotides 50-3454 and thus would hybridize under high stringency conditions (limitations of Claim 5). Pulst also teaches a nucleic acid sequence which is 100% identical to the nucleic acid sequence of SEQ ID NO: 2 (limitations of Claim 6). Pulst also teaches a nucleic acid sequence which is 77.9% identical to the sequence of SEQ ID NO: 4 (limitations of Claim 6). While SEQ ID NO: 2 positions 163-4098 have priority to October 1996, the entire claim is provided the date of May 1997.

Thus for the reasons above and those already of record, the rejection is maintained.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a nucleic acid which has at least 90% homology to the SCA2 coding portion of SEQ ID NO: 2 and 4.

The specification teaches SEQ ID NO: 2 and 4 coding positions.

The specification fails to teaches nucleic acids which are 90% identical with these sequences.

There is not adequate description of the genus nucleic acids which are 90% identical with the coding portions of SEQ ID NO: 2 and 4. The specification only discloses two nucleic acids within the scope of the genus: nucleic acids which are 90% identical with these sequences. The nucleic acids described are not representative of the genus nucleic acids which are 90% identical with these sequences. There is substantial variability among the species of nucleic acids encompassed in the scope of the claim. The specification has also not defined a structural feature of the nucleic acids which would be common to all members of the genus that constitutes a substantial portion of the genus. The claim encompasses allelic variants which have not been described. Furthermore, one of skill in the art would conclude that applicant was not in possession of the claimed "nucleic acids which are 90% identical with these sequences" because the description of only two members of this genus is not representative of the nucleic acids of the genus and is insufficient to support the claims. Thus, the specification does not adequately provide a written description for nucleic acids which are 90% identical with these sequences.

Claim Rejections - 35 USC § 102

10. Claims 5-6, 62-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Gispert (Nature Genetics, 1993).

The claims are drawn very broadly to any nucleic acid which hybridizes under high stringency conditions to 1-516 of SEQ ID NO: 1, 163-4098 of SEQ ID NO: 2 or 50-3454 of SEQ ID NO: 4.

Gispert et al. (herein referred to as Gispert) teaches the chromosomal assignment of SCA2, cerebellar ataxia 2, to chromosome 12q23-24.1. Chromosome 12 has been isolated and analyzed (limitations of Claims 1-2).

It is noted that theses smaller segments of nucleic acid outlined in the claims would hybridize to the chromosomal region which is described in Gispert.

Therefore since Gispert teaches every limitation of the instant claims, Gispert reads on the claimed invention.

11. Claims 5-6, 62-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Pulst et al. (Nature Genetics, 1993).

The claims are drawn very broadly to any nucleic acid which hybridizes under high stringency conditions to 1-516 of SEQ ID NO: 1, 163-4098 of SEQ ID NO: 2 or 50-3454 of SEQ ID NO: 4.

Pulst teaches the further localization of SCA2 to a 8.9 cM region, between IGF1 and D12S105/S84, with a maximum lod score of 3.6 (limitations of Claims 1-2).

It is noted that theses smaller segments of nucleic acid outlined in the claims would hybridize to the chromosomal region which is described in Pulst.

Therefore since Pulst teaches every limitation of the instant claims, Pulst reads on the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable Imbert et al. (Nature Genetics, November 1996) or Pulst et al. (Nature Genetics, November 1996) in view of Orr et al. (US. Pat 5,741,645, April 1998).

Imbert et al. (herein referred to as Imbert) teaches a polypeptide of 90 amino acids which is encoded by the nucleic acid of SEQ ID NO: 5. The nucleic acids from between 921-1190 of the instant application are 100% identical to the amino acids from 207-296. Imbert teaches a nucleic acid sequences which is 99.8% identical to SEQ ID NO: 1 nucleotides 1-499 and thus would hybridize under high stringency conditions (limitations of Claim 5). Imbert teaches a nucleic acid sequence which is 88.1% identical (ie., substantially the same nucleotide sequence) to the nucleic acid sequence of SEQ ID NO: 2 with a best local similarity of 98.5%.

Pulst et al. (herein referred to as Pulst) teaches a nucleic acid which is 99.8% identical to the nucleic acid sequence of SEQ ID NO: 1 nucleotides 1-499 and thus would hybridized under high stringency conditions (limitations of Claim 5). Pulst also teaches a mouse sequence which is 100% identical to the nucleic acid sequence of SEQ ID NO: 4 nucleotides 50-3454 and thus would hybridize under high stringency conditions (limitations of Claim 5). Pulst also teaches a nucleic acid sequence which is 100% identical to the nucleic acid sequence of SEQ ID NO: 2 (limitations of Claim 6). Pulst also teaches a nucleic acid sequence which is 77.9% identical to the sequence of SEQ ID NO: 4 (limitations of Claim 6). Oligonucleotides were end-labelled, FISH was performed and cDNA clones were isolated with P-labelled probes (pg. 275, col. 1)(limitations of Claim 11). Pulst teaches several different methods for identifying nucleic acids encoding SCA2 protein including FISH, and hybridization of (CAG)10 oligonucleotides followed by cloning and sequencing (pg. 275)(limitations of Claim 37). Pulst also teaches primers which were derived from SEQ ID NO: 2 and SEQ ID NO: 4 (pg. 275, para. 6).

Neither Imbert nor Pulst specifically teaches a vector or host cell containing the SCA2 nucleic acid.

However, Orr et al. (herein referred to as Orr) teaches a SCA1 gene which was isolated to the short arm of chromosome 6 (abstract). Orr also teaches that a gene probe is used for detecting the presence of a DNA sequence located within a SCA1 gene. The method includes digesting genomic DNA with restriction endonucleases to obtain DNA fragments, separating the fragments by size, probing the DNA fragments by

size with a detestably labeled probe, and detecting the probe which hybridized to DNA fragments to analyze the DNA for (CAG)n regions characteristic of the normal or affected SCA1 gene (col. 2, lines 50-63)(limitations of Claim 37). Probes used for identifying DNA segments are labeled with radioactive or nonradioactive labels (col. 6, lines 20-43). Primers which hybridize to SCA1 genes on either side of the CAG repeat region, including directly adjacent to the CAG regions are disclosed (col. 3, lines 1-14)(limitations of Claim 40). Orr teaches a method of cloning a purified 1.2-kb fragment into a pBluescript plasmid (col. 10)(limitations of Claim 7).

Therefore, it would have been **prima facie** obvious to one of ordinary skill in the art at the time the invention was made to have modified the teachings of Pulst or Imbert to include the teachings of Orr in order to make the invention. The ordinary artisan would have been motivated to insert the SCA2 gene into a vector and host cell, as taught by Orr, for the convenience of storing the gene and for the further cloning of the gene. Orr has been merely used to illustrate nucleic acids may be inserted in vectors for the convenience of storing the gene and for the further cloning of the gene.

Allowable Subject Matter

13. Claim 61 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

14. Claims 59, 61 appear allowable over the art. The prior art does not teach the SCA2 nucleic acid from the mouse which are SEQ ID NO: 4 and 5 (limitations of Claims

59 and 61).

Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Enewold Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Thursday from 7:00AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jeanine Enewold Goldberg
March 29, 2001

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600

4/9/01